DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 18, 2014

Suzhou Weikang Medical Apparatus Co., Ltd.
c/o Mr. Mike Gu
Regulatory Affairs Manager
OSMUNDA Medical Device Consulting Co., Ltd.
7th Floor, Jingui Business Building,
No. 982 Congyun Rd., Baiyum District
Guangzhou, Guangdong 510420
CHINA

Re: K140228
Trade/Device Name: Disposable Tracheal Tube
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: November 12, 2014
Received: November 14, 2014

Dear Mr. Gu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K140228

Device Name: Disposable Tracheal Tube

Indications for Use:

Disposable tracheal tube is intended for oral or nasal intubation and for airway management.

Prescription Use __x____ AND/OR Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____
_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

I. SUBMITTER

Suzhou Weikang Medical Apparatus Co., Ltd.

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Quality Director

Suzhou Weikang Medical Apparatus Co., Ltd.

Date Prepared: 21 January, 2014

II. DEVICE

Name of Device: Disposable tracheal tube

Common/Usual Name: Tracheal tube

Classification Names: Tracheal tube, 21 CFR 868.5730

Regulation Class: II

Product Code: BTR

III. PREDICATE DEVICE

Weikang is claiming substantial equivalence to the following medical devices:

Well Lead Endotracheal Tube – K042683

Well Lead Reinforced Endotracheal Tubes-k073383

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

- The tracheal tubes are disposable and are supplied sterile. The tracheal tubes are available in a number of sizes/variants. All variants are primarily made from polyvinyl chloride. The tracheal tube without cuff is composed of a tubular body and a standard connector, and the cuffed tube is composed of tubular body, cuff, one-way valve, pilot balloon, inflating tube and standard connector. All variants have a Murphy eye. As the device functions in airway management/gas transport for anesthesia or resuscitation, it is required to be flexible and resistant to kinking. All variants have a radio-opaque line embedded into the tube which enables identification the device when the patient is X-rayed.

V. INDICATIONS FOR USE

Disposable tracheal tube is intended for oral or nasal intubation and for airway management.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The disposable tracheal tubes are made from biocompatible, non-toxic polyvinyl chloride material. The lumen is embedded with radio-opaque line to assist locating the device when the patient is X-ray viewed. The tracheal tube is designed with a Shore hardness of 88A to resist kinking and to ensure effective intubation.

The disposable tracheal tubes employ the same technology as its predicate devices Well Lead Endotracheal Tube (K042683) and Well Lead Reinforced Endotracheal Tubes (k073383).

The following technological differences exist between the subject and predicate devices:

- Size of tracheal tubes used for airway management.
- Same material but similar hardness degree;

Though these technological elements are slightly different, both the subject and predicate device meet the requirements of ISO 5361:2012 Standard.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Performance testing:

Essential performance and safety requirements and continuous wave resistance of the shaft of the tube are evaluated according to the following standard respectively:

- ISO 5361:2012
- ISO 11990-1: 2011

The testing results demonstrate that the proposed devices meet the requirements of the standards listed above.

Biocompatibility testing:

The biocompatibility evaluation for the disposable tracheal tubes was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The probe is considered as external communicating device in contact with tissue with cumulative contact up to 24 hours.

Animal and clinical study

The subject of this premarket submission, disposable tracheal tubes, does not require clinical

studies to support substantial equivalence.

VIII. CONCLUSIONS

The non-clinical data support the safety of the device and the performance testing results demonstrate that the disposable tracheal tubes should perform as intended in the specified use conditions. Suzhou Weikang Medical Apparatus Co., Ltd considers the disposable tracheal tubes do not raise any new issues of safety or effectiveness.